

## SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>GUATEMALA</b>	2. DATE OF BIRTH			2a. AGE <b>76 Years</b>	3. SEX <b>Female</b>	3a. WEIGHT <b>62.00 kg</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>						<b>OCT</b>	<b>2023</b>	<input type="checkbox"/> PATIENT DIED  <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING  <input type="checkbox"/> CONGENITAL ANOMALY  <input checked="" type="checkbox"/> OTHER
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) <b>Other Serious Criteria: Medically Significant</b> <b>Fall [Fall]</b> <b>Fainting [Fainting]</b> <b>Broke a rib [Rib fracture]</b> <b>Diagnostic of high cholesterol problems [High cholesterol]</b> <b>Very low blood pressure [Blood pressure low]</b> <b>Very slow palpitation [Palpitation]</b> <b>Diagnostic of brain aneurysm [Aneurysm cerebral]</b>  Case Description: This solicited case was received in GUATEMALA and (Continued on Additional Information Page)											

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1 ) INDAPAMIDE 1.5MG-F37 (INDAPAMIDE 1.5 mg) Coated tablet, 1.5 mg #2 ) Bisoprolol (Bisoprolol)		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1 ) 1.5 mg, qd #2 ) UNK	16. ROUTE(S) OF ADMINISTRATION #1 ) Oral use #2 ) Unknown	
17. INDICATION(S) FOR USE #1 ) Hypertension (Hypertension) #2 ) Heart problems (Cardiac disorder)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 2023 / 26-JUL-2025 #2 ) DEC-2023 / JUN-2025	19. THERAPY DURATION #1 ) Unknown #2 ) Unknown	

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1 ) Atorvastatin (Atorvastatin) ; Unknown #2 ) Glisulin (Metformin hydrochloride) ; 2023 / Ongoing		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates 2023 to Ongoing Unknown to Ongoing	Type of History / Notes Historical Condition Historical Condition	Description Hypertension (Hypertension) Prediabetes (Glucose tolerance impaired)

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER SERVIER CENTRO AMERICA Y CARIBE PANAMA		26. REMARKS Patient ID: 1573073601609 Study ID: IC4-06520-001-GTM*
	24b. MFR CONTROL NO. <b>S25011241</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>30-JUL-2025</b>	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT <b>06-AUG-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

**ADDITIONAL INFORMATION****7+13. DESCRIBE REACTION(S) continued**

concerned a patient participating in the Patient Support Program (PSP) (IC4-06520-001-GTM) (Improve adherence to treatments). The initial reporter was a Consumer.

The patient was a 76-year-old female (Weight: 62 kg, Height :157 cm) with the medical history of Hypertension since unknown date in 2023, treated with INDAPAMIDE 1.5MG-F37 (1 tablet daily, orally) from unknown date in 2023 to 26-JUL-2025. Cardiac problems since an unknown date treated with BISOPROLOL (unknown daily dose) from an unknown date in DEC-2023 to an unknown date in JUN-2025. High cholesterol since an unknown date treated with Atorvastatin (unknown daily dose), Prediabetes since an unknown date treated with Metformin hydrochloride (unknown daily dose) since an unknown date in 2023.

No other concomitant treatment was reported, if any.

On an unknown date in MAY-2025, patient was diagnosed with high cholesterol problems. The intensity and to what she related it to were not obtained.

On an unknown date in JUN-2025, patient experienced a Fainting, they took her blood pressure and saw that it was very low due to INDAPAMIDE 1.5MG-F37 and she had very slow palpitations.

The palpitations may have been related to Bisoprolol 5mg. The intensity was not obtained. Because of this fainting, the patient broke a rib, from which she has already recovered.

On an unknown date in JUN-2025, she experienced a fall and she was hospitalized (dates were not obtained). The intensity of the event and the causal relationship with INDAPAMIDE 1.5MG-F37 were not obtained.

On an unknown date in OCT-2023, she was diagnosed with brain aneurysm, It was not obtained to what she related it to, she maintained this diagnosis stable.

Treatment of Diagnostic of high cholesterol problems: Since unknown date, she took Colmibe 20mg, 1 tablet daily.

Action taken with INDAPAMIDE 1.5MG-F37: Drug withdrawn.

Outcome: Not recovered from High cholesterol problems and brain aneurysm.  
Unknown for Very low blood pressure, fainting, palpitations, and Fall.  
Recovered for Rib fracture.

The case was reported as serious for event Fall (Hospitalization), and Event Fainting was upgraded to serious (Medically significant) by pharmaceutical company.

The reporter's causality assessment was related for low blood pressure, not related for brain aneurysm, rib fracture and fainting, slow palpitation and unknown for high cholesterol and Fall.

Consent to contact the doctor was not obtained.

Case Comment: Hypotension and syncope are listed in the RSI of INDAPAMIDE, while rib fracture, blood cholesterol increased, palpitations and intracranial aneurysm are unlisted. Given the reasonable chronology and pharmacological plausibility, the causal role for fall, syncope, hypotension and palpitations is assessed as possible. Since blood cholesterol increased is a metabolic disorder which can be associated with co-morbidities, the causal role is assessed as unlikely. Due to the nature of the events (trauma-related, vascular structural disorder), the causal role for rib fracture and intracranial aneurysm is assessed as not related.

**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAY-2025	Blood cholesterol		
		high cholesterol problems		

**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Heart disorder (Cardiac disorder);
MAY-2025 to Ongoing	Historical Condition	High cholesterol (Blood cholesterol increased);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
---------------	-------------------------	-------------